

Remarks/Arguments

Applicants provisionally elect Group I and the species provided by SEQ ID NO: 1. The election is made with traverse. Claims 1-6, 8, 9, and new claims 33-46 are within Group I and read on the elected species. The provided claim listing indicates "withdrawn" for those claims not within the elected Group and species.

The present response includes, without prejudice to future prosecution, the cancellation of non-elected claims 11-16, 19, 22, 23, 26, 28, and 30-32; and the addition of claims 33-46. The cancellation of claims was made to offset the number of new claims.

New claims 33-36 further describe SEQ ID NO: 1 related polypeptides. Support for claims 33-36 is provided in the application, for example, on page 12, line 33 to page 13, line 1.

New claims 37-46 are directed to a pharmaceutical composition of claims 3 and 33-36. Support for claims 37-46 can be found, for example, on page 3, lines 7-10, and the Original claims.

Additional Data

The results in the application include examples illustrating the ability of different *E. coli* expressed ORF0657nH and ORF0657nI to provide protection using BALB/C mice, and the ability of Yeast expressed ORF0657nH to provide protection using BALB/C mice. Additional experiments performed after the application was filed using yeast expressed ORF0657nI indicates there is some variability in whether or not protection is seen depending upon the model used to evaluate protection.

Yeast expressed ORF0657nI provided protection when present by itself in ICR Mice, provided protection with endotoxin in BALB/C mice, but did not provide protection by itself in BALB/C mice. (See Additional Protection Data Table.)

Additional Protection Data Table

	BALB/C mice		ICR Mice
	Yeast Expressed + Endotoxin	Yeast Expressed - Endotoxin	Yeast Expressed
ORF0657nI	Protective	Not protective	Protective

Endotoxin by itself was not protective.

In all cases aluminum hydroxyphosphate adjuvant was used.

The results described in the application and the additional protection data are attributed to the presence of endotoxin and the BALB/C mice model. The purification procedure employed in the application for obtaining ORF0657nI from *E. coli* contained both ORF0657nI and endotoxin. The yeast produced ORF0657nI did not contain endotoxin. It appears that in the BALB/C mice model the endotoxin provided an adjuvant affect for ORF0657nI.

The application also indicates fragments made up of SEQ ID NO: 2 amino acids 461-609, 82-486 and 42-196 were not protective. (The present application at page 8, lines 19-20). These fragments were expressed in, and obtained from, *E. coli*. It was not determined whether the tested fragments 1, 2 and 3 contained endotoxin.

Provided Restriction Requirement

The restriction requirement restricted the claims as follows:

- I. Claims 1-6, 8 and 9 drawn to a polypeptide immunogen comprising an amino acid sequence at least 90% identical to SEQ ID NO: 1 without amino acid 609-645 of SEQ ID NO: 2 and a composition comprising the same;
- II. Claim 7, drawn to an immunogen consisting of an amino acid sequence at least 90% identical to SEQ ID NO: 1 linked to a moiety (inclusive of SEQ ID NO: 2);
- III. Claims 10-17, 27 and 28 drawn to a nucleic acid comprising a nucleotide sequence encoding the polypeptide of invention I;
- IV. Claims 18 and 29-32 drawn to a method of making a *S. aureus* polypeptide using a recombinant cell comprising the nucleic acid of invention III;

- V. Claims 19-24 drawn to a method of inducing a protective immune response in a patient by administering an amount of the polypeptide of invention I; and
- VI. Claims 25 and 26, drawn to a method of inducing an anamnestic response comprising administering a polypeptide immunogen comprising an amino acid sequence at least 90% identical to SEQ ID NO: 1.

The restriction requirement argues that a special technical feature of invention I is lacking based on a sequence comparison between WO 200259148 accession number ABJ19106 and SEQ ID NO: 1. The special technical feature of invention I discussed in the restriction requirement is a polypeptide immunogen comprising an amino acid sequence at least 90% identical to SEQ ID NO: 1, where if one or more additional polypeptide regions are present the regions do not provide a carboxyl terminus containing amino acids 609-645 of SEQ ID NO: 2 and the polypeptide provides protective immunity against *S. aureus*.

The restriction requirement further argues that: (1) the polypeptide of invention II and the nucleic acid of invention III do not share significant structural elements with the polypeptide of invention I, as a polypeptide comprises amino acids while a nucleic acid comprises purine and pyrimidine subunits; and (2) the methods of inventions IV, V and VI do not share significant steps, parameters, products used, method objectives, and/or ultimate goals accomplished.

Traversal of Restriction Requirement

It is respectfully submitted that WO 200258148, accession number ABJ19106 contains amino acids 609-645 at its carboxyl terminus and, thus, is not covered by claim 1. Accession number ABJ19106 corresponds to the full-length protein expected to include at its carboxyl terminus amino acids 609-645 of SEQ ID NO: 2. Claim 1 excludes SEQ ID NO: 2. The sequence listing provided in the office action appears to be a comparison of SEQ ID NO: 1 and accession number ABJ19106 up to amino acid 486 of ABJ19106.

The restriction requirement provided comments concerning inventions I, II and III, and the structural difference between a nucleic acid and polypeptide. Invention II while not excluding SEQ ID NO: 2, indicates the immunogen comprises an amino acid sequence at least 90% identical to SEQ ID NO: 1. Invention III is directed to a nucleic acid sequence.

Additional comments on the restriction requirement are provided below. The additional comments include reference to different claims including or excluding SEQ ID NO: 2. It is respectfully submitted that claims excluding SEQ ID NO: 2 be grouped with Group I.

Group II: Independent claim 7 is directed to an immunogen comprising an amino acid sequence at least 90% identical to SEQ ID NO: 1, wherein said immunogen consists of said amino acid sequence and one or more additional regions moieties. As indicated by the examiner, Claim 7 is inclusive of SEQ ID NO: 2. SEQ ID NO: 2 contains amino acid 609-645 at its carboxyl terminus.

Group III: Claims 10 and 17 exclude SEQ ID NO: 2. Claim 27 is inclusive of SEQ ID NO: 2. Independent claim 27 is directed to a yeast optimized nucleic acid sequence encoding an ORF0657n related polypeptide that provides protective immunity against *S. aureus* infection, or a fragment thereof comprising an amino acid sequence at least 90% identical to SEQ ID NO: 1.

Group IV: Claim 18 excludes SEQ ID NO: 2. Claim 29 does not exclude SEQ ID NO: 2. Independent method claim 29 (Group IV) refers to making a polypeptide that is a full-length ORF0657n related polypeptide that provides protective immunity against *S. aureus* infection, or a fragment thereof comprising an amino acid sequence at least 90% identical to SEQ ID NO: 1.


Group V and VI: Claims 20 (Group V) and 25 (Group VI) are inclusive of SEQ ID NO: 2. Independent method claims 20 and 25 both involve using a polypeptide comprising an amino acid sequence at least 90% identical to SEQ ID NO: 1, and do not exclude SEQ ID NO: 2.

Claim 21 (Group V) excludes SEQ ID NO: 2. Claim 21 depends on claim 20 and indicates the immunogen of claim 1.

Claim 19 appears to belong with Group IV, not group V. Claim 19 further describes the method of making a polypeptide provided by claim 18. Claim 19 was canceled without prejudice to future prosecution.

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If any time extensions are needed for the timely filing of the present amendment, applicants
petition for such extensions and authorize the charging of deposit account 13-2755 for the
appropriate fees.

Respectfully submitted,

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